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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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MATTHEW A. NEWBOLES
STETINA BRUNDA GARRED & BRUCKER
Suite 250
75 Enterprise
Aliso Viejo, CA 92656

EXAMINER	
NGUYEN, BAO THUY L	
ART UNIT	PAPER NUMBER
1641	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/09/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/695,297	CHUNG ET AL.	
	Examiner	Art Unit	
	Bao-Thuy L. Nguyen	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 November 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)

2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3)☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.

4)☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.

5)☐ Notice of Informal Patent Application

6)☐ Other: _____.

DETAILED ACTION

1. The amendment filed 21 November 2006 has been received.

2. Claims 1-8 are pending.

3. All rejections not reiterated herein below are withdrawn in view of Applicant's arguments.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1 and 5 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Van Hoegaerden (US 5,405,784) for reasons of record.

Van Hoegaerden discloses fluorescent latex beads having more than one antiligands fixed to their surface. The antiligands are specific to more than one substances or ligands to be sought. See column 3, lines 27-68 and column 4, lines 16-22. See also column 10, example 5; column 11, example 8, and claims 8 and 11. Even though Van Hoegaerden does not specifically state that the antiligands or the derivative haptens are "ligand analog protein", these designations are seen to be the same since the antiligand of Van Hoegaerden is defined as molecular structure capable of

recognizing and binding specifically to the organic, biological or medicinal substances to be detected. Van Hoegaerden also teaches that the beads are suitable for direct, indirect sandwich or competitive assays.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 2-4 and 6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Van Hoegaerden in view of Chudzik et al (US 5,981,298) and The Triage Panel for Drugs of Abuse, Biosite Diagnostics, 1991.

See the discussion of Van Hoegaerden above. These references differ from the instant invention in failing to teach conjugating morphine-3-beta-D-glucuronide or amphetamines to the dye particles.

Chudzik, however, discloses reagents and method for detecting the presence of one to four drugs in a single sample of urine or serum such as cocaine, amphetamines, their derivatives and metabolites (column 3, lines 66 through column 4, line 5; and column 4, lines 64 through column 5, lines 5). Chudzik teaches conjugating gold sol

particles or dyes with drug conjugates (column 6, lines 51-65), such as morphine, morphine glucuronide, amphetamines, etc. (column 9, lines 21-35).

The Triage Panel teaches that is desirable detect drugs of abuse because they continues to be an increasingly significant social and economic problem. Opiates, cocaine, THC, amphetamines as well as other tranquilizers, anti-depressants, barbiturates and opiate compounds can all be detected using visually read immunoassays. The triage Panel discloses monoclonal antibodies against the major metabolites of phencyclidine, amphetamines, opiates, barbiturates etc. for use in immunoassay and further discloses an extensive list of drugs that may be tested including morphine-3-β-glucuronide.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the affinity reagents taught by Van Hoegaerden to include ligand analog such as morphine glucuronide and amphetamine since Chudzik and The Triage Panel teach that such conjugates are well known in the art. A skilled artisan would have had a reasonable expectation of success in replacing the derivative hapten taught by Van Hoegaerden with the ligand analog of morphine or amphetamine as taught by Chudzik and The Triage Panel because such a change is a mere alternative and functionally equivalent conjugation technique.

Even though these references do not specifically teach that the particulate dye is conjugated with 3, 4 or 5 different ligand analogs, such a reagent is obvious in view of the teachings of Van Hoegaerden, Chudzik and The Triage Panel. Each of these

references recognize the needs for detecting more than one analytes in the same sample and provide reagents and means for doing so.

Response to Arguments

8. Applicant's arguments filed 21 November 2006 have been fully considered but they are not persuasive.

Applicant argues that Van Hoegaerden does not teach ligand analog protein instead, Van Hoegaerden teaches fluorescent beads that binds directly to the substances to be detected which is in sharp contrast to the method of Applicant's claimed invention where the particular dye includes ligand analog protein complexes and further includes ligand receptors capable of binding either to the ligand of interest or the ligand analog protein complexes on the particulate dye.

These arguments have been fully considered but are not persuasive. The instant invention is drawn to a particle having absorbed thereon, at least two different ligand analog proteins. The ligand analog proteins bind with receptors that are also specific for first and second ligands.

Since "ligand analog" is not specifically defined in the specification, an art accepted definition was used. Specifically, "analog" is defined by the American Heritage Dictionary as "something that bears an analogy to something else; or a structural derivative of a parent compound". Additionally, neither the claims or the

specification specifically defined "ligand analog protein complexes" therefore, this "complex" is seen as the ligand analog protein itself.

Using this definite, Van Hoegaerden discloses the same particle. Van Hoegaerden teaches fluorescent beads coated with a derivative of the hapten aflatoxin-poly-L-lysine (column 10, lines 28-36) for use in a competitive assay. As stated previous and agreed by Applicant, Van Hoegaerden discloses beads with at least two different ligands immobilized thereon. Clearly, "a derivative of the hapten aflatoxin-poly-L-lysine" meets the definition of a "ligand analog protein". Even though Van Hoegaerden did not choose to call the hapten a "ligand analog protein", one can clearly see that they are one and the same.

The argument that Van Hoegaerden does not teach particulate dye having ligand analog protein complexes and ligand receptors capable of binding either to the ligand of interest or the ligand analog protein complexes on the particulate dye is not persuasive.

The claims do not recite a particular dye having a ligand analogue protein and a *ligand receptor* for said protein.

The argument that the method taught by Van Hoegaerden is not the same with those of the instant invention is not persuasive. The claims are directed to a particle and not a method, therefore, it is irrelevant how the particle is used. Even if one were to give weight to the method, the instant ligand analog proteins are recited as binding to *receptors for the first and second ligands*, which is the same as the hapten taught by Van Hoegaerden.

Applicant argues that because the independent claim is shown not to be anticipated by Van Hoegaerden, dependent claims 2-4 and 6-8 are allowable for the reason that these claims depend on allowable independent Claim 1 and because these claims recite additional features that further define the present invention.

This argument is not persuasive. Van Hoegaerden anticipates the instant claim 1 and is therefore not allowable.

Even though Van Hoegaerden and the Triage Panel as well as Chudzik do not specifically teach that the particulate dye is conjugated with 3, 4 or 5 different ligand analogs, such a reagent is obvious in view of the teachings of Van Hoegaerden, Chudzik and The Triage Panel. Specifically, Van Hoegaerden teaches that the beads have one or *more* ligand, antiligand or ligand analog absorbed thereon. Clearly, this disclosure encompasses beads having 3, 4 or 5 different species absorbed thereon. Furthermore, each of these references recognize the needs for detecting more than one analytes in the same sample and provide reagents and means for doing so, therefore the instant particles are obvious over teachings of Van Hoegaerden, Chudzik and The Triage Panel.

Conclusion

9. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Bao-Thuy L. Nguyen
Primary Examiner
Art Unit 1641 2/2/07